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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/469,606	12/22/99	VOLLMERS H.	PATWA-2

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EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/469,606	Vollmers et al
Examiner	**Art Unit**
Anne Holleran	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 21, 2001* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) *5-29* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. The preliminary amendment filed March 31, 2000 is acknowledged. However, the amendment to claim 9 was not entered because the phrase "one of claims 5 to 8" was not present in claim 9.

Election/Restriction

2. Applicant's election with traverse of group I, claims 1-4, in Paper No. 8, filed February 21, 2001, is acknowledged. The traversal is on the ground(s) that a search of the glycoprotein of claims 1-4 would be the same for the product as for the methods of the remaining claims. This is not found persuasive because other considerations and searches are required to search the methods. As there are more than one method of use of the claimed products, a search of multiple methods would be an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

AUH 6/30/01

3. Claims 1-29 are pending.

Claims 5-29, drawn to non-elected inventions, are withdrawn from consideration.

Claims 1-4 are examined on the merits.

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Germany on 05 March 1999 and 22 December 1998. It is noted, however, that applicant has not filed a certified copies of the German applications as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

5. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it refers to a compound as having a primary amino acid sequence without providing the amino acid sequence. The specification also fails to provide an amino acid sequence of CD55.

6. Claims 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Reproduction of an antibody with the identical properties to those of monoclonal SC-1, and reproduction of a cell line with identical properties to those of 23132 are unpredictable events. Therefore, the specification fails to teach one of skill in the art how to make the antibody of claim 2 and the cell line of claim 4. A deposit of monoclonal antibody SC-1 and of the cell line 23132 is required. The specification does not indicate that the monoclonal antibody SC-1 has

been deposited and the description of how to make the SC-1 monoclonal antibody is inadequate to reproduce an antibody with the same properties as that of SC-1. Although the specification provides depository information for cell line 23132, the specification lacks complete deposit information for the deposit of adenoma carcinoma cell line 23132. There is no assurance that cell line 23132 is freely available without restriction.

Thus, it is not clear from the disclosure that the deposit of cell line 23132 meets all the criteria set forth in MPEP 608.01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

In the case of monoclonal antibody SC-1, because one of ordinary skill in the art cannot be assured of the ability to practice the claimed invention in the absence of the availability of antibody SC-11, a suitable deposit for patent purposes, evidence of public availability of antibody SC-1, or evidence of the reproducibility, without undue experimentation, of the antibody SC-1 is required.

If the deposit is made under the provision of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be

replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the Budapest Treaty as the treaty leaves this specific matter to the discretion of each member state.

If the deposits are not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) states that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

(b) states that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

(c) states that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

(d) acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

Amendment of the specification to recite the date of deposit is required. Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Applicant's attention is also drawn to the following: unless the deposit was made at or before the time of filing, a declaration filed under the 37 C.F.R. 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited SC-1 monoclonal antibody by its depository accession number, establish that the deposited SC-1 is the same as that described in the specification, and establish that the deposited SC-1 was in applicant's possession at the time of filing.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Medof et al (Medof, M.E. et al, J. Exp. Med. 160: 1558-1578, 1984) as evidenced by Hensel et al (Cancer Research 59: 5299-5306, 1999).

Claim 1 is drawn to a glycoprotein comprising CD55 and a tumor-specific glycostructure. Claim 2 further limits claim 1 in that the glycoprotein binds to monoclonal antibody SC-1. The specification asserts that CD55 is the same protein as DAF.

Medof teaches the purification of DAF from human erythrocytes. As evidenced by Hensel, DAF possess the inherent property of binding the SC-1 monoclonal antibody. Thus, Medof teaches a glycoprotein that is the same as that claimed.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuji (U.S. 5,695,945; issued 9 Dec. 1997) as evidenced by Hensel et al (Cancer Research 59: 5299-5306, 1999).

Tsuji teaches purification of DAF from human blood (column 3, lines 6-29). As evidenced by Hensel, DAF possess the inherent property of binding the SC-1 monoclonal antibody. Thus, Tsuji teaches a glycoprotein that is the same as that claimed.

9. Claims 1-4 are rejected under 35 U.S.C. 102(a) as being anticipated by Hensel et al (Hensel, F. et al., Cancer Res. 59: 5299-5306, 1999, October; cited in the IDS).

Applicant has not perfected the claim to foreign priority. Upon perfection of foreign priority, and provision of English language translations of the foreign priority documents, this rejection will be withdrawn.

Hensel teaches the purification of the CD55/DAF (pages 5299). Hensel teaches the isolated glycoprotein has a molecular weight of 82 kDa. Hensel teaches a method for obtaining the glycoprotein from adenoma carcinoma cell 23132 membranes. Thus, Hensel teaches glycoproteins and methods as claimed.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
June 30, 2001

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